



Grantees interested in participating in training workshops and follow-up onsite help may contact Audrey Smolkin (asmolkin@hrsa.gov) for referrals and further information.

October 2, 2001

THE 340B DRUG DISCOUNT PROGRAM

Jimmy Mitchell, Director of HRSA's Office of Pharmacy Affairs (OPA), spoke to grantees on October 2, 2001 about the Section 340B Drug Discount Program, one of the many programs offered by the OPA. Enacted in 1992, section 340B of the Public Health Service Act requires drug manufacturers to provide pharmaceuticals to eligible health care centers, clinics and hospitals at a reduced price.

As Mr. Mitchell emphasized, the 340B program is often referred to by other names, such as PHS, 602, or DSH price, all of which refer to the same program. The 340B discounted price is a "ceiling price", meaning it is the highest price a covered entity would have to pay for a particular drug. Manufacturers may not sell at a higher price, but are permitted to offer a lower price whenever possible. The 340B price is also at least as low as the Medicaid price that state agencies pay.

Eligibility

There are a number of different types of clinics eligible for the 340B program. Some of these include Federally Qualified Health Centers (FQHCs), AIDS clinics, Urban Indian clinics, FQHC look-alikes, and the outpatient clinics of certain disproportionate share hospitals (DSHs).

For a complete list of the types of eligible organizations, please go to the OPA website at <http://www.hrsa.gov/odpp>, click on "How to Enroll in 340B", and review the "Which Grant Programs are Eligible" section.

Requirements and Prohibitions

The main requirement of the program relates to the definition of the patient who receives the discounted drugs: An eligible patient is an individual who depends on the outpatient services of the covered entity, uses providers affiliated with the entity, and maintains his/her medical records with that same entity. In essence, the covered entity is completely responsible for that patient's care. Discounted drugs may not be provided to patients who do not meet these requirements.

There are two primary prohibitions in the program:

- 1. No double-dipping:** A covered entity may not request 340B prices for the same drug for which Medicaid would request a reimbursement from the drug manufacturer.

- 2. Control drug distribution:** A covered entity may not do anything with a drug except dispense it to eligible patients under relevant and accepted programs. Drugs may not be sold to non-patients.

Program Benefits

Most participants of the 340B Drug Discount Program save an average of 25-50 percent on covered outpatient drugs. These savings allow covered entities to improve their health care delivery programs by:

- Reducing the price of medications for patients
- Expanding the number of outpatient drugs offered
- Increasing the number of patients served, particularly indigent patients
- Increasing the number of physicians and providers in the network
- Expanding other services offered

The potential discount increases with the number of entities that join the program. A larger number of participating entities give the Prime Vendor greater negotiating power with the manufacturers. Therefore, joining the program does not just benefit the organization that joins, but all of the other organizations that participate in the program as well.

Prime Vendor

According to the original legislation, a “prime vendor” had to be established as the single preferred wholesaler that serves covered entities in the 340B program. AmerisourceBergen (formerly Bergen-Brunswig Drug Corporation) was awarded the contract in September 1999. The prime vendor is responsible for managing the delivery of 340B drugs to covered entities, as well as using the collected volume of the multiple participants to negotiate an even lower sub-ceiling price with the drug manufacturers. According to Mr. Mitchell, as many as 2700 drugs have been negotiated for an average of 17 percent below the ceiling price, resulting in significant savings on quality pharmaceuticals for participating entities.

The prime vendor may also assist participants by offering value-added services on a fee-for-service basis. Some of these include:

- Computer support
- Pharmacy management consultation and drug information
- Drug repackaging
- Computerized indigent patient drug assistance programs

Additional information on the 340B Prime Vendor Program can be found on the OPA website at <http://www.hrsa.gov/odpp>.

Getting Started

According to Mr. Mitchell, a price comparison is available for entities that are interested in the program but need to know if it will provide enough savings to warrant application. Entities can provide the OPA with a list of up to 50 pharmaceuticals that they currently purchase. The list should be organized by NDC code and submitted in Microsoft Excel format. That list will be compared with the current 340B prices, and the OPA will then

return an estimate of savings within a 10 percent range. Actual prices cannot be provided until the entity officially joins the program.

Before getting started, a covered entity must notify the OPA of its desire to participate in the program. Organization representatives may call 1-800-628-6297 to obtain official enrollment forms. Once eligibility is determined, the entity must provide its Medicaid billing status, which falls under one of three categories:

1. The entity bills Medicaid separately for its pharmaceuticals (if it does bill Medicaid it must submit that billing number to the OPA).
2. The entity does not bill Medicaid.
3. The entity bills Medicaid at an all-inclusive rate.

This information must be provided before the entity can be enrolled in the program. Once the application is approved, the program can start at the beginning of the next fiscal quarter.

Mr. Mitchell cautioned grantees against getting further information about the program by word of mouth. He encouraged use of the OPA web site as a reliable resource for additional restrictions, guidelines, and helpful hints that were not covered in this discussion.

For More Information:

Office of Pharmacy Affairs

<http://www.hrsa.gov/odpp>

Phone: 1-800-628-6297

AmerisourceBergen

<http://www.amerisourcebergen.net>

CALL PARTICIPANTS:

Name	Organization
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Angelique Raptakis	Management Assistance Corporation
Anita Lee	Ambulatory Care
Anne Kircher	Sangre de Cristo Community Health, NM
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Brenda Theus	Shelby County Health Care Corporation, TN
Candi Gebler	First Choice Community Healthcare, Inc
Carolyn Emanuel	Family Health Center, SC
Chris Mahler	HRSA
Christine Ayman	Synthesis Professional Services
Cindy Oakes	Cabarrus Community Care Plan
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Connie Floerchinger	Central Indiana Health System
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